Health Information Technology Policy Committee
Final
Summary of the March 2, 2011, Meeting

KEY TOPICS

1. Call to Order

Judy Sparrow, Office of the National Coordinator (ONC), welcomed participants to the 21st meeting of the Health Information Technology Policy Committee (HITPC). She reminded the group that this was a Federal Advisory Committee meeting being conducted with the opportunity for public comment, and that a transcript would be made available on the ONC Web site. She asked Committee members to introduce themselves, and turned the meeting over to HITPC Chair David Blumenthal, the National Coordinator for Health Information Technology.

2. Opening Remarks

Blumenthal said that since the last meeting, some of those present had attended the Healthcare Information and Management Systems Society (HIMSS) meeting, and judging from the size of that event, the federal government seems to be having an impact. The industry is growing. He noted that the HITPC will be asked to consider recommendations from its Information Exchange Workgroup. It may be necessary to hear that report, provide Committee members with time to review the recommendations, and then conduct a teleconference to vote on them. The ONC will be in touch with Committee members and will keep them informed.

3. Review of the Agenda

HITPC Vice Chair Paul Tang called for a motion to approve the minutes from last month's HITPC meeting—the minutes were approved by consensus. He then reviewed the day's agenda and introduced Quality Measures Workgroup Co-Chair David Lansky.

> **Action Item #1:** Minutes from the February 2, 2011, HITPC meeting were approved by consensus, with a correction by Paul Tang that was sent to Judy Sparrow.

4. Quality Measures Workgroup: Results

Lansky presented an update on the Quality Measures Workgroup's progress related to enhancing quality measures. A set of materials was included in Committee members' meeting packet, reflecting a substantial amount of input the Workgroup has now received from the public and from professionals to advance public health IT.

The Workgroup has reviewed Stage 1 quality measure objectives as well as the structure of the Stage 1 menu set that allowed specialties to pick measures that were meaningful to them. Now,

they are developing a larger library of measures to address the domains that they have talked about in past meetings. One of the upcoming tasks is to evaluate whether there is an opportunity to change the reporting structure in light of a new pool of measures in development.

In Stages 2 and 3, there will be at least two new bundles of measures to consider for evaluating quality performance. These are ONC *de novo* measures, and an additional 69 measures that have been retooled for electronic health records (EHRs). These will go through a harmonization process with other federal programs for quality measurements, so that they do not chase after things that are already incorporated into other programs. After this process, the Workgroup will come back before the Policy Committee for decisions about which objectives are appropriate for meaningful use Stages 2 and 3.

As a reminder, Lansky presented the domain framework for stage 2 meaningful use, which includes: (1) clinical appropriateness/efficiency, (2) population and public health, (3) patient and family engagement, (4) care coordination, and (5) patient safety. There are sub-domains and measure concepts for each of the above areas. ONC staff and potentially others will review the concepts, and consider which could be developed to work in the meaningful use program for Stages two and three.

Lansky noted that some of these concepts were discussed in greater detail at the last meeting, reminding Committee members that there are methodological considerations that cut across some of these concepts. Some proposed measures are longitudinal: they must be taken, perhaps from different data systems, and compared to one another. This is valuable from the point of view of care coordination, but will require some methodological consideration.

With this Committee's support, the ONC will continue to develop these proposed measures and identify those that are viable. The Office will then initiate measure development activities, and then those concepts and measures suitable for Stage 2 would be put out for public comment. In 2012, at the completion of Stage 2, the ONC will start to look at stage 3.

Lansky then reviewed the policy issues that remain for the HITPC to consider:

- Framework for Stage 2 clinical quality measures (CQMs), including balancing core measures with "specialty" measures and Stage 1 and a "retooled" measure set.

- Exchange and interoperability infrastructure to facilitate implementation of innovative measures (e.g., standardized transition of care document, ability to incorporate longitudinal data).

- Available infrastructure for patient-reported outcomes.

- Available standards and vocabulary.

Discussion

- Blumenthal thanked the Workgroup for the huge amount of work involved in boiling down and organizing the hundreds of suggestions they received. This process will give the federal government the chance to consider a broader range of measures than they had in Stage 1, and the opportunity to be more representative of the actual practice of health and medicine, including the representation of more specialties in the measures. They will be watching what Centers for Medicare and Medicaid Services (CMS) does in areas including medical homes, so that the federal government sends as consistent a message as possible about what its priority measures are. He hopes that by working with private stakeholders, there will be some alignment between the government and private sectors in pay for performance and quality improvement measures. He characterized a consistent set of measures that are collectible electronically and rooted to the right target, as payers and policymakers decide on their priorities, as the "holy grail." This work is a critical foundational component of enabling that future to be realized.

- Gayle Harrell asked about the process and the timing related to development of the *de novo* measures. Tom Tsang of ONC explained that the process started about 6 months ago, when the ONC began getting feedback on what would be feasible and possible. Now, the Office is funneling in those with the Request for Proposal (RFP) comments, and narrowing down to the most promising measures based on the evidence being gathered. Next, a master contractor will work with federal agencies and such entities as the National Quality Forum (NQF) to consider feasibility and the consensus body picture. Regarding time frame, they will be looking at what measures are going to be feasible within an 8-month to 1-year time frame for Stage 2. Those that will not be ready will be considered for Stage 3.

- In response to a question, Blumenthal explained that there are many coordinating mechanisms in place, including an interagency group of quality and an electronic quality measure group representing multiple organizations. Also, the rulemaking process will enable the public to comment. As they have seen, that comment period sometimes causes significant changes to their view. The ONC has no desire to perpetuate the collection of outmoded and non-useful information. That said, they are going to have to transition into electronically empowered measures, because not everybody is going to be electronically capable right away.

- Larry Wells noted that in the President's Council of Advisors on Science and Technology (PCAST) Report there is a notion of focusing on atomic data. The value of that is being able to feed quality measures. He asked Lansky for thoughts about what this atomic data might be and wondered whether they are looking more broadly at what systems can be doing in this regard. Lansky said that they have not gotten to that level of analysis. One of the issues this raises is where such computation would take place. Who is the aggregator of data across providers? The more granular that data is expected to be, the more often the question arises of who owns that aggregated data.

- Tom Tsang commented that as they start developing this universe of e-measures they will need a standard dictionary. The ONC is trying to develop that data model, and is working

closely with the NQF on evolving the quality data model (QDM). If they can get to a universal, granular group of vocabulary sets that could be the foundation of all quality measures, then most of that computational work could be done at the provider level. How that will be reported and aggregated will be a policy issue.

- Paul Egerman asked what will happen with the information collected in the measurements for Stage 2. Will it be transmitted to CMS, or will it just be attested to? Lansky explained that attestation is easier to implement. Ultimately, they hope it will be reported, but there are several stages to go through in order to report publically, and that is not an inherent part of meaningful use. CMS's Tony Trenkle acknowledged that they are looking at this issue in terms of timing and infrastructure.

- Neil Calman suggested that it is easy to become more concerned with getting quality reporting systems in place and losing sight of what anyone will actually do with this collected data. He emphasized that their goal is to improve quality, and not just look at quality. He is troubled by the assumptions being made that public reporting is going to improve quality, and that once people have this quality information, they are going to be somehow embarrassed by it and want to improve. Calman suggested that most people do not even look at this information. He emphasized the need to be parsimonious, because organizations can only focus on improvements in a few areas at a given time. Also, they must start thinking on a policy level about how to connect these measures with something that actually drives the actual meaningful use of the resulting information. To the extent that they keep aiming for a broad set of many of measures, they might be moving in a direction where everybody is measuring the same thing, instead of truly stimulating the local use of data to drive improvement in areas that a particular provider would find useful.

- Paul Tang explained that measures are potent by their credibility. One of the things that has been limiting them is the available information, which up to now as been mostly claims and administrative data, which are not that potent with clinicians. There is now an opportunity, with the conversion to EHRs, to create new, credible measures that physicians will actually believe. Some of the *de novo* measures fit that bill. Parsimony is also clearly important given the realities of human attention. Transparency will be key, in that any physician's scores can be examined, at first within an organization but ultimately by the public. Credibility, parsimony, and transparency will make the endeavor effective.

- In response to comments questioning particular timing and logistical issues, Blumenthal made the point that this group is the only one in the federal government that is focusing on harnessing the powers of electronic measures of health care. Even though there are issues of timing and issues of exchange that may or may not be in place, and despite the many practical constraints, he urged the Committee to keep moving forward, because the system will catch up.

- The Committee endorsed the direction of the workgroup's efforts, and approved the notion of the work continuing.

Action Item #2: The Committee endorsed the efforts of the Quality Measures Workgroup.

5. Privacy and Security Tiger Team Discussion on Authentication of Users

Blumenthal introduced the discussion, and Privacy and Security Tiger Team Co-Chair Paul Egerman walked the Committee through slides offering technical definitions. Tiger Team Chair Deven McGraw then discussed user authentication policy, reminding Committee members that the Team does not expect authentication to be the linchpin of security; it is just one element of it. They assume that provider entities have taken care of the identity component, having provided credentials and adequately addressed security. She reviewed Health Insurance Portability and Accountability Act (HIPAA) security rules relating to authentication.

The National Institute of Standards and Technology (NIST) has set different levels of assurance that are aligned with what would occur if there was an authentication error. Low is level one; high is level four. The most relevant application to this discussion is the interim final rule for the prescription of controlled substances, which has come from the Drug Enforcement Administration (DEA.) Level three assurance was selected, implying a relatively high degree of confidence that the individual is who they say they are. The Tiger Team's recommendation is modeled after this work, and requires two-factor authentication.

Beginning with the use case of remote access, which creates some heightened security concerns, the Tiger Team felt that level three was appropriate. It was emphasized that all health data is sensitive data. Also, the general sense is that a single factor of authentication would not be enough. The Team has not reached consensus yet on whether to set a baseline policy requirement regarding which factors ought to be required.

Egerman walked the group through the questions that this work raised with the Tiger Team:

- Should two-factor authentication of remote EHR users be required? If so, should the types of factors to be considered be specified?

- Is single-factor authentication adequate in combination with a rigorous password management program?

- Should baseline requirements vary by level of risk of access?

- Should the Tiger Team's recommendation for remote users also apply to enterprise (in-house) users?

Discussion

- Tony Trenkle pointed out that sometimes in an effort to minimize risk, one actually increases it by making the process too difficult. People will find ways to get around the passwords. Egerman concurred that security efforts sometimes do more harm than good, saying that in some cases users have to sign on to so many different systems that they tape the names and

passwords right to the devices. Otherwise, it would simply be too much to remember. He said that there are changes happening with regard to two-factor authentication that are showing potential, more so than on the biometric side.

- McGraw said that the challenge for them is to create a policy recommendation that does not focus on one technological solution, but that leaves room for some market innovation and would allow organizations to choose the solution that would work best for them.

- Gayle Harrell emphasized the need for the public's trust. Part of the issue has been a lack of provider education about security issues. Also, she said that there needs to be an education component for the public. Whatever course of action they decide upon, they need to make sure everyone understands it.

- Judy Faulkner suggested that when physicians are on call, they may be in the position of having to make critical decisions quickly. Perhaps there is a way that the system can recognize who is on call, and have a different level of security for them, to make it quicker. One level of authentication has already been established, in that they are identifying the on-call physician.

- Blumenthal commented that many of the western European countries have arrived at solutions to these authentication issues. They may not be transferable to the United States, but ONC staff should be able to support the Tiger Team in becoming familiar with those. Also, the question of utility or convenience is not a fixed property, and not a physical law. People will deal with inconvenience if they see the value in putting up with it, and if they are convinced that the trouble is worth it. He does not think they have spoken sufficiently to the provider community, many of whom could be naïve to this discussion. Blumenthal referred to a recent discussion he had with the Deputy Administrator at CMS for program integrity, and he pointed out that there is a significant problem associated with physician identity theft. Scammers steal physician identities so that they can set up illegal billing operations. So one utility for physicians—one reason to put up with inconvenience—is to ensure the ability to protect themselves from identity theft.

- Paul Tang noted that every organization he knows of uses two-factor authentication. With thousands of physicians, that has not been a problem.

- Larry Wells said his experience differs from Tang's, with about a one-third of the organizations he works with using just single-factor authentication. They are looking at less invasive ways to provide a second factor. He suggested that it might be useful to get more field experience: what are the causes for security breaches? Are they mostly technical or are they related to human error? That way, when they put safeguards in place, they are addressing the real problems.

- Marc Probst said that he does not believe two-factor authentication should be required. There is technology now that makes it possible to look at exactly how a physician used data, and whether it was appropriate use. He is hesitant to require a specific approach when technology is changing so rapidly that one might have a single-factor approach that is as

good or better than two-factor. His advice is to establish a level of assurance rather than specifically naming one-factor, two-factor, etc.

- Judy Faulkner asked about using biometrics. Egerman explained that NIST does not accept biometrics, and that there are controversies surrounding it.

- Paul Tang suggested that the group examine a law that was discussed about 10 years ago relating to digital signatures. McGraw pointed out that the National Strategy for Trust and Identity in Cyberspace has an ongoing national initiative on this subject. People are looking at this beyond the health care sphere, and it is relevant to what this group is doing but on a different timetable.

- Egerman asked whether the group should be looking at access in the direct enterprise, in addition to remote access. Blumenthal said yes, that it is part of the process, and the Tiger Team's thoughts on the subject would be valuable.

6. PCAST Report Workgroup Update

PCAST Report Workgroup Chair Paul Egerman briefly summarized the group's recent hearings, presenting the following common themes: (1) the PCAST Report is not well understood, (2) there is an absence of consensus within the industry, (3) privacy and security is a recurrent theme, and (4) there are timeframe-related concerns.

The Workgroup is starting to coalesce around what the main issues are, and what ONC's alternatives might be around each of these issues. The more difficult challenge is determining how all of the recommendations in the PCAST Report fit into meaningful use. Three different approaches were discussed: (1) UEL approach, (2) pilot approach, and (3) market approach. This is a work in progress, and the Workgroup has a 3-hour meeting planned for the day after this Committee meeting to discuss these approaches. A final report will be presented to the HITPC at its next meeting on April 13, 2011.

Discussion

- Gayle Harrell noted that she found the lack of discussion about the PCAST Report at HIMSS to be fascinating. She is somewhat distressed in that they are now on a pathway, and spending money, and she hopes they are spending it in the right direction. Her sense is that people viewed the report as more aspirational, and not as much as a roadmap. She urged caution in going in too specific a direction for Stage 2 if there is any likelihood that there will be a change in direction later.

- Larry Wells said that in the three options, he sees top down, bottom up, and middle out approaches.

- David Blumenthal noted that the PCAST Report conveys an enormous sense of urgency, with the message that if they do not act by Stage 2 of meaningful use, something valuable and irretrievable will be lost, a certain architecture will be frozen in place, and

interoperability will never be accomplished. He is interested in knowing whether the Workgroup sees a similar timeframe. Egerman posed an interrelated question: is what PCAST saying really all that different from ONC is already doing? He said there are some technical differences, but in some ways it is surprisingly close to what is already taking place.

7. Information Exchange Workgroup Recommendations for Individual Level Provider Directories (ILPDs)

Paul Tang introduced the Information Exchange Workgroup presentation, proposing that the Committee postpone any decisions about the material until the next meeting, because Committee members had only recently received the materials to review. Workgroup Co-Chair David Lansky framed the discussion by explaining that provider directories for both entities and individuals had been taken on by the Workgroup, with task forces set up for each one. At this meeting, recommendations for individual-level provider directories.

Walter Suarez, Co-Chair of the Provider Directory Task Force, presented the series of recommendations. He explained that the Task Force developed a framework for discussing directories at the entity level, and they are using that same framework to consider ILPDs. The ILPD recommendations generally fell into wither recommended practices and areas required to enable basic interoperability. Recommendations in the following areas were presented: (1) participants, (2) users, (3) content, functional capabilities, (4) operational requirements, (5) cost and business model considerations, and (6) policy considerations

Discussion

- Paul Tang noted that one issue is protecting against identity theft. The information presented by the Workgroup did not specify how it is to be protected, only that it needs to be protected.

- Deven McGraw asked about what specific policy levers are being recommended. For example, should all meaningful users be listed in an ILPD?

- Gayle Harrell warned that this directory would be an excellent source of information for fraudulent individuals. Security issues must be emphasized. She also asked what the ongoing source of funding for this directory will be, noting that ongoing operating costs will be significant.

- One Workgroup member said that, speaking from the state health information exchange (HIE) perspective, there is clamoring from the states for structure. What they would like goes well beyond what this group is prepared to offer at the national level. In the Workgroup, they are trying to lay out useful directions and best practices. People are now at a formative stage with this, and there are some key, minimal things that will need to be taken forward through standards work to get a more fine-tuned set of recommendations.

- Neil Calman pointed out that NPI numbers and license numbers are already available on the Web. They are not secure pieces of information now.

- Larry Wells asked if more information about identity should be incorporated. Also, in addition to the fact that states are doing this for their own initiatives, he pointed out that there is also the Direct Project, which is a federal effort. He asked that the Workgroup address this component. He also noted that one of the fundamental use cases is going from provider to provider, but in many cases the receiver is in the same office as the sender.

- Jodi Daniel suggested that it would be helpful to understand which items are best practices versus "must-haves." Also, are there specific things that should be tied to governance as a baseline requirement? How are these connected with some of the other activities that are happening?

- Paul Tang suggested that the Workgroup divide out the issues that should be brought before the HIT Standards Committee versus key policy aspects.

8. Public Comment

- Carol Bickford from the American Nurses Association (ANA) pointed out that when the ANA looked at the quality measure report relating to pressure ulcers, they were looking across the full care spectrum, not just in the hospital. This raises the question of whether there are other conditions that were incorrectly characterized.

- Mike Peters from the American College of Radiology voiced the need for imaging information in EHRs. Radiology practices are already beyond the tipping point for electronic imaging. He also said that meaningful use is not truly meaningful for radiologists and other specialty providers. This must be addressed in Stage 2. He understands why this happened in Stage 1, but the lack of discussion for Stage 2 is a concern. Stage 2 rulemaking is the last chance to get it right before it becomes an unfunded mandate for specialists.

- Bill Braithwaite of Anakam Inc. said that it is a question of the strength of passwords, not their size or complexity. It is about the fact that they can be guessed, so they must be non-dictionary, non-named kinds of passwords. Passwords by themselves are powerful, but people have had to resort to writing them down, which makes them risky. Whether biometrics alone is sufficient depends on a number of factors. Biometrics requires a reader, an interpreter. It is a question of whether or not the device can be compromised by malware or spoofed by some mechanism. The same considerations would apply to patient and provider applications.

- Corinne Rubin from the American Academy of Ophthalmology made a comment about the ILPD and the recommendation of filtering the information with PECOS. She urged caution until CMS's infrastructure is able to handle that information. A lot of information that has been posted since January is incorrect or out of date. They need to think about whether CMS has the adequate infrastructure so that data can be updated in a timely fashion.

- Imran Chowdhury from Opixia suggested that, with regard to passwords, the first time a doctor logs on in the morning would be an appropriate time to double-check identity, but not

all day. Also, with regard to biometric solutions, she asked about what happens if the biometric database gets compromised.

- Jonah Houts from Express Scripts voiced specific concern about e-prescribing. It is well known that e-prescribing has benefitted patients and hospitals. Unfortunately, 18 different states are creating legislation that would create a patchwork of standards. These standards cannot be supported by the current standards that have been developed, and may lead to a great deal of confusion. This is a difficult issue for providers, who will face a 1 percent cut in Medicare reimbursement next year if states adopt these standards, and a difficult issue for legislators and organizations such as the HITPC, which must realize that these standards can be modified on a state-by-state basis.

SUMMARY OF ACTION ITEMS:

Action Item #1: Minutes from the February 2, 2011, HITPC meeting were approved by consensus, with a correction by Paul Tang that was sent to Judy Sparrow.

Action Item #2: The Committee endorsed the efforts of the Quality Measures Workgroup.